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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,161

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Andreas Habich

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CONNOLLY BOVE LODGE & HUTZ, LLP

P O BOX 2207

WILMINGTON, DE 19899

EXAMINER

BADR, HAMID R

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,161	Applicant(s) HABICH ET AL.	
	Examiner HAMID R. BADR	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-22, 25, 26 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-22, 25-26, 34-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed 12/15/2009 is acknowledged.

Claims 1, 4-22, 25-26, 34-42 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4-9, 11-20, 25-26, 34-38, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bewert et al. (5,318,903; hereinafter R1) in view of Soeda et al. (US 6,030,821; hereinafter R2) and Bedford et al. (2000, Enzymes in Farm Animal Nutrition; hereinafter R3)

3. R1 discloses a process for the production of dry, free flowing enzyme preparations by spraying aqueous enzyme dispersions which may contain additives. (Abstract).

4. R1 discloses the enzyme dispersions to be converted into dry, stable enzyme preparations which can be employed in the food and animal feed industries. (Col. 1, lines 46-49). R1 discloses that the enzymes (including phytase) used may be of animal, plant, and microbial origin. (Col. 2, lines 1-9)

5. R1 discloses mixing an aqueous phytase with soybean meal and water. The resulting suspension is sprayed and the moist product is dried in a fluidized bed. The activity of phytase in the product is 350 FTU/g. (Col. 3, Example 1).

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6. It is noted that the activity of phytase in the final product depends on the initial input activity, therefore; at higher input activity of phytase, the final product can be produced to contain higher phytase units per gram as presently claimed.

7. Given that soybean meal is used for making the enzyme dispersion, it is clear that the phytase enzyme will be in association with plant carbohydrates (e.g. starch) and proteins (soybean protein). Liquid enzyme preparations containing phytase are also known and prepared in the art. Methods of enzyme granulation and enzyme granules are also well known in the art.

8. While R1 discloses the incorporation of soybean meal into the enzyme preparations, R1 is silent regarding the additives such as isolated plant protein and presently claimed. R1 is also silent regarding the thermal stability of the phytase in phytase preparations.

9. R2 discloses the stabilizing effect of proteins, protein hydrolysates and particularly isolated plant proteins such as wheat protein, soybean protein etc. (Col. 2, lines 12-29). R2 then discloses the use of separated (isolated) soybean protein in stabilizing enzymes. (Table 1).

10. R2 is generally silent regarding the heat stability of the enzyme preparation.

11. R3 discloses the thermal stability of phytase and states that depending on the enzyme source the thermal stability can vary between 45C to 77C. (paragraphs under phytase, paragraphs 1, 2). R3 discloses that the interaction of the enzyme with the feed matrix will protect the enzyme from steam or elevated temperature. Further, R3 teaches

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that measuring phytase activity in pelleted feed provides a more accurate evaluation of the commercial importance of inactivation. (paragraph 3).

12. Other processing methods such as extrusion (low and high pressure), granulation, agglomeration, spheronization and drum granulation for the production of pellets or granules containing enzymes including phytase are also known in the art. Mixing and kneading the enzyme with the solid carrier and the stabilizing agent are also known processes in the art.

13. R3 discloses that thermal protection of available exogenous enzymes by encapsulation or granulation provides a solution at present. (paragraph 5).

14. R1 and R2 disclose that an enzyme such as phytase can be stabilized by additive components comprising carbohydrates and isolated plant proteins. R3 discloses that these components can protect the enzyme from thermal denaturation that the enzyme encounters upon pelleting or thermal processing. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to stabilize phytase through incorporation of isolated plant protein and carbohydrates (both components were known protein stabilizing agents at the time the invention was made). One would do so to protect phytase, added to the food or feed, from thermal stress encountered during processing such as pelleting, drying or granulation or enzyme wear and tear during storage. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making pellets or granules containing stabilized active phytase.

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15. Claims 10 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1-R3 as applied above, further in view of Harz et al. (US 7,556,802; hereinafter R4).

16. R1-R3 are silent regarding coating enzyme containing granules.

17. R4 discloses a process for producing a polymer coated , granulated, enzyme containing feedstuff additive and pelleted feedstuff compositions which are produced with the polymer coated additives. (Abstract).

18. R4 discloses the granulation process comprising slurring the mass to be granulated, extrusion, spheronising, and drying. (col. 2, lines 53-66).

19. R4 discloses the coating of a phytase containing granule. (Col. 9, Example 2).

20. Therefore, it would have been obvious to make phytase containing granules and coat them as taught by R4. One would do so to protect the phytase containing granules against environmental factors such as moisture.

21. Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1-R3 as applied above, further in view of Cheng et al. (US 5,985,605; hereinafter R5) and Andela et al. (US 2003/0054511; hereinafter R6).

22. R1-R3 are silent regarding promoting the growth of an animal by using phytase containing food or fee.

23. R5 discloses a method for improving phosphorus utilization by the animal by feeding an effective amount of phytase. Phytate phosphorus utilization may be evidenced by, for instance improved animal growth as presently claimed. (Col. 4, lines 46-54).

24. R5 is silent regarding the feed conversion rate when phytase is used in the feed.
25. R6 discloses methods for improving the feed conversion rate by reducing the anti-nutritional effects of certain feed compounds. Feed enzymes such as phytase may also be used to reduce the amount of compounds which are harmful to the environment. Given that phytates are anti-nutritional factors in animal feed and knowing the function of phytase in hydrolyzing the phytates, inclusion of phytase in animal feed with the concomitant improvement in the feed conversion rate would have been obvious to an artisan.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that R1 uses soybean meal not an isolated plant protein.
 - a. Please see the new ground of rejection for the teachings of the new reference regarding the use of isolated plant proteins as enzyme stabilizing agents.
2. Applicants argue that Bedford (now R3) does not remedy the deficiencies of R1.
 - a. According to the teachings of R2, the enzyme stabilizing effect of isolated plant proteins was known at the time of invention. Additionally it was also known that carbohydrates, proteins etc., feed components, also have stabilizing effects against heat. The enzyme stabilizing effect of proteins is a well known and old concept. Applicants can refer to Determann et al. (US 4,118, 279) where they explain that protein preparations have proved to be especially useful as enzyme stabilizing agents. (Col. 1,

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lines 13-17). Therefore, stabilizing enzymes through the used of proteins is not a new concept.

3. Applicants' arguments involving other claims and references are now moot due to the new ground of rejection concerning claim 1 regarding stabilized phytase preparations.

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794